

REMARKS

Status of Claims

Independent claim 43 is the sole pending claim in this application. The claim has been amended to recite a “method for treating wrinkles and/or fine lines.” Support for the amendment can be found throughout the specification as filed, including, for example, the Abstract and paragraph [0057], both of which describe a “treatment composition,” and more specifically in the working example provided on page 15, line 15–page 19, line 1, which discloses clinical results on the treatment of wrinkles and fine lines. Accordingly, the amendment raises no new matter issues.

Claim Rejections

Obviousness

The Examiner rejects claim 43 under 35 U.S.C. §103(a) as obvious over Brunengraber et al. (WO 98/51277) in view of Chambers, et al. (WO 97/27835), Tanaka, et al. (JP 09030946), Babish, et al. (WO 96/17605), Chiou, et al. (*British J. of Pharmacology* 2000 129:1553-1560), and Shen, et al. (*Planta Medica* 2000 66:314-317). Briefly, the Examiner alleges that Brunengraber discloses that compounds which act as antioxidants, have anti-inflammatory activity, and inhibit reactive oxygen species or nitric oxide, also can reduce skin aging and wrinkling; while Shen and Chiou allegedly teach that andrographolides inhibit reactive oxygen species and nitric oxide. The Examiner does not discuss Chambers. Tanaka is relied on as teaching use of andrographolides for skin lightening; and Babish for teaching that *Andrographis* contains andrographolides. The Examiner contends that one of ordinary skill in the art would have expected andrographolides to be suitable for topical application to reduce skin aging and wrinkling. Applicants respectively traverse these rejections.

The Examiner's contention is essentially that because Brunengraber discloses that the specific compound pyruvate can function as an anti-inflammatory and antioxidant, and is said to prevent wrinkles, it would therefore have been obvious to use any antioxidant or anti-inflammatory compound to combat wrinkles. This contention is factually and legally unsupportable because (i) it amounts to the improper application of the “obvious to try” doctrine in the unpredictable field of development of chemical actives, See Takeda Chemical Indus. v.

Alphapharm, 492 F.3d 1350 (Fed. Cir. 2007); Ortho-McNeil Pharma. v. Mylan Labs., 520 F.3d 1358 (Fed. Cir. 2008); Eisai Co. v. Dr. Reddy's Labs., 533 F.3d 1353 (Fed. Cir., July 21, 2008); and (ii) it grossly oversimplifies “inflammation” in suggesting that all anti-inflammatories would behave similarly, whereas inflammation is one of the most complex and diverse biological processes, implicating a host of plasma-derived mediators (e.g., the kinin system, fibrinolysis system, and coagulation system) and cell-derived mediators (e.g., TNF- α , histamine, prostaglandin, etc.). In sum, the rejection is improper because the cited references, and the rationale proffered by the Examiner, would not have given one skilled in the art a reasonable expectation that andrographolide could reduce the appearance of wrinkles. See MPEP § 2143.02(I); In re Merck & Co., Inc., 800 F.2d 1091 (Fed. Cir. 1986); In re O'Farrell, 853 F.2d 894, 903 (Fed. Cir. 1988). Aspirin and corticosteroids are both anti-inflammatories, but it cannot reasonably be contended that the activity of one would predict the activity of the other in view of their different biochemical modes of action. Here, the Examiner has made not attempt to explain why the results obtained with pyruvate would be predictive of andrographolides other than to simply state that andrographolide is an antioxidant and anti-inflammatory. Withdrawal of the rejection is warranted for at least this reason.

Moreover, claim 43 is amended to recite a “method for treating wrinkles and/or fine lines,” distinguishing merely preventative uses. While it may be possible to prevent or retard wrinkle formation with antioxidants, there is no known mechanism by which antioxidants can treat wrinkles that have already manifest. Consistent with this, Brunengraber relates to prophylaxis rather than treatment, disclosing that pyruvate can function as an anti-inflammatory and antioxidant, which may be useful for the “protection of the skin against oxidative injury.” See, page 20, lines 29-30. By referring to protecting against damage, Applicants respectfully submit, Brunengraber is referring to preventing the development of future wrinkles, or to preventing the worsening of existent wrinkles, but not to reversing the appearance of existing wrinkles on the skin.

The other cited references cannot cure this deficiency. Chiou and Shen, for example, never mention wrinkling, Tanaka teaches skin lightening rather than wrinkling, and Chambers and Babish likewise are completely devoid of any teachings regarding skin wrinkling. As none of the cited art references remotely teach or suggest the use of andrographolide or its derivatives

for treating (rather than preventing) wrinkling, as required by the amended claim, there can be no prima facie case of obviousness. Accordingly, Applicants respectfully submit that claim 43, as amended, fully distinguishes over the art of record, for at least any one of the above reasons, and earnestly and respectfully request reconsideration and withdrawal of the obviousness rejection.

CONCLUSION

Applicants respectfully submit that the instant application is in condition for allowance. Entry of the amendments and an action passing this case to issue is therefore respectfully requested. In the event that a telephone conference would facilitate examination of this application in any way, the Examiner is invited to contact the undersigned at the number provided.

Respectfully submitted,

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